

### REMARKS

The Examiner rejected claims 1-37. To further prosecution and simplify any remaining issues for appeal, claims 1-37 have been cancelled herein without prejudice, and claims 40-42 have been added. New claim 40 recites an implantable medical device comprising a stent, a non-woven framework attached to the stent, and *in vitro* seeded cells within the non-woven framework. Claim 40 also recites that (1) the non-woven framework comprises stainless steel fibers and pores having an average size of at least 40  $\mu\text{m}$ , (2) the non-woven framework is not coated with an extracellular matrix protein, and (3) the implantable medical device is implantable within the vascular system of a mammal via percutaneous deployment. Claim 41 recites that the cells express a polypeptide selected from the group consisting of vascular endothelial growth factor, natriuretic peptide, prostacyclin synthase, angiostatin, endostatin, erythropoietin, and a marker polypeptide. Claim 42 recites that the stent is balloon expandable or self-expanding.

Applicants' specification fully supports these new claims. For example, page 2, lines 13-24 as well as page 7, lines 15-22 disclose an implantable medical device comprising a stent and a non-woven framework attached to the stent. Page 8, lines 6-8 and page 13, lines 11-13 disclose that cells can be seeded *in vitro* within the non-woven framework. Original claim 13 discloses that the non-woven framework can comprise stainless steel fibers; original claim 21 discloses that the polypeptide can be selected from the group recited in new claim 41; and original claim 29 discloses that the stent can be balloon expandable or self-expanding. In addition, the section extending from page 13, line 24 to page 14, line 6 discloses that the non-woven framework can be coated or uncoated with fibronectin, an extracellular matrix protein. Page 6, lines 16-17 and page 15, lines 29-31 disclose that stents can be inserted via percutaneous deployment. Thus, no new matter has been added.

In light of these new claims and the following remarks, Applicants respectfully request reconsideration and allowance of claims 40-42.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-26, 28, and 31-37 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Applicants respectfully disagree. To further persecution and simplify any remaining issues for appeal, claims 1-26, 28, and 31-37 have been cancelled herein without prejudice. Thus, this rejection is moot.

The Examiner also rejected claims 1-26, 28, and 31-37 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a stent being the medical device that is balloon expandable, does not reasonably provide enablement for another medical device that is balloon expandable. Applicants respectfully disagree. To further persecution and simplify any remaining issues for appeal, claims 1-26, 28, and 31-37 have been cancelled herein without prejudice. Thus, this rejection is moot.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 28 and 29 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully disagree. To further persecution and simplify any remaining issues for appeal, claims 28 and 29 have been cancelled herein without prejudice. Thus, this rejection is moot.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected (1) claims 12, 14-20, and 26-29 under 35 U.S.C. § 103(a) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069) in view of Healy *et al.* (U.S. Patent No. 5,670,161), (2) claims 21-23 under 35 U.S.C. § 103(a) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069) in view of Healy *et al.* (U.S. Patent No. 5,670,161) and further in view of Ferrara *et al.* (U.S. Patent No. 6,455,283), (3) claims 1-7, 9-11, 13, 24, 25, and 30-34 under 35 U.S.C. § 103(a) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069) in view of Healy *et al.* (U.S. Patent No. 5,670,161), Ducheyne (U.S. Patent No. 5,030,233), and Cottone *et al.* (U.S. Patent No. 5,824,043), and (4) claims 8 and 35-37 under 35 U.S.C. § 103(a)

as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069) in view of Healy *et al.* (U.S. Patent No. 5,670,161), Ducheyne (U.S. Patent No. 5,030,233), and Cottone *et al.* (U.S. Patent No. 5,824,043) in further view of Ferrara *et al.* (U.S. Patent No. 6,455,283). Specifically, the Examiner repeatedly stated that it would have been obvious to form the tubular structure of Vacanti *et al.* as a stent made from non-woven fibers.

Applicants respectfully disagree. The combinations of references do not render the previously claimed invention obvious. To further prosecution and simplify any remaining issues for appeal, claims 1-37 have been cancelled herein without prejudice. Thus, these rejections are moot.

New independent claim 40 recites an implantable medical device comprising a stent, a non-woven framework attached to the stent, and *in vitro* seeded cells within the non-woven framework. Claim 40 also recites that (1) the non-woven framework comprises stainless steel fibers and pores having an average size of at least 40  $\mu\text{m}$ , (2) the non-woven framework is not coated with an extracellular matrix protein, and (3) the implantable medical device is implantable within the vascular system of a mammal via percutaneous deployment. A person having ordinary skill in the art reading the previously cited references would not have been motivated to make or use such an implantable medical device. In fact, at no point does the combination of previously cited references teach or suggest making an implantable medical device comprising a non-woven framework attached to a stent. Likewise, at no point does the combination of previously cited references teach or suggest making an implantable medical device comprising a non-woven framework attached to a stent where the non-woven framework comprises stainless steel fibers and *in vitro* seeded cells and is not coated with an extracellular matrix protein. Thus, a person having ordinary skill in the art reading the combination of previously cited references would not have been motivated to make the presently claimed invention.

### CONCLUSION

Applicants submit that claims 40-42 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned attorney at the telephone number

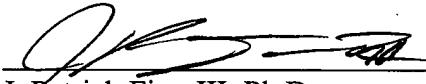
Applicant : Noel Caplice et al.  
Serial No. : 09/843,295  
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below if such will advance prosecution of this application. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: February 7, 2005

  
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